

REMARKS

1. Status of Application

The status of the application referred to in the priority claim has been updated and corrected. No new matter has been added. Priority is now correctly established to the proper patent applications.

2. Specification Amendments

Page 2, line 11 should be "or" as originally phrased in the specification.

Page 5, line 31, "filed" has been changed to "field". The appropriate correction was made.

Page 17, lines 16-28, Applicant has added a very brief description of FIG. 1. All of the materials inserted therein is obvious from or directly disclosed in FIG. 1. Specifically, as FIG.1 is a typical laser apparatus, elements 5-9, 11-12, 14, 15, 20 and 30 are obvious from a brief examination of FIG. 1 and the text originally describing FIG. 1. No new matter has been added.

3. Drawing Correction

Applicant has inserted a limited, minimum amount of text describing elements 5-9, 11-12, 14, 15, 20, 30, and 40. These elements were described as exactly as shown in FIG. 1 and are obvious to those with ordinary skill in the art from the drawing. No new matter was added.

Applicant has removed reference number 10 from FIG. 1 as this component was not directly referenced in the specification. A substitute drawing is attached herewith.

4. Claim Amendments.

The claims have been amended to remove minor typographical errors. These clarifications should address the examiner's 35 USC 112 concerns and Applicant requests that the examiner withdraw the objection to Claims 14-17, 24 and 37 based on 35 USC 112. No new matter has been added to the claims.

The patent application was originally filed with the payment of a filing fee for 45 total claims and 3 independent claims. After the amendments herein, there still are 45 total claims and 3 independent claims, and no additional fee is necessary.

5. Disclaimers

a. Claims 1, 3-7 and 9-18

Applicant has filed a terminal disclaimer, in accordance with 37 CFR 1.321(c), that disclaims any portion of the term connected with Claims 1, 3-7, 9 and 9-18 that extends beyond the end of the term of Myerson '406. See Attached Disclaimer. As such, Applicant requests that the examiner withdraw the rejection based on the judicially created doctrine of obviousness type double patenting over the claims of Myerson '406.

b. Claims 1, 3-7, 9 and 11-18

Applicant has filed a terminal disclaimer, in accordance with 37 CFR 1.321(c), that disclaims any portion of the term connected with Claims 1, 3-7, 9 and 11-18 that extends beyond the end of the term of Myerson '935. See Attached Disclaimer. As such, Applicant requests that the examiner withdraw the provisional rejection based on the judicially created doctrine of obviousness type double patenting over the claims of Myerson '935.

6. Inventorship

A. Conflicting Inventions

Applicant submits that because Claim 1 now is allowable (see the amendment to Claim 1 above and the discussion of the allowability of Claim 1 below), and Terminal Disclaimers have been filed in regard to the inventors' cited patent and patent application, the point raised by the examiner regarding Claims 5-7 and 15 being obvious over Myerson '935 is moot. Thus, Applicant requests that the examiner's rejection of Claims 5-7 and 15 over Myerson '935 be withdrawn.

B. Inventorship

All subject matter claimed in the above-identified patent application has been invented by both of the listed inventors.

7. 35 USC 102 Rejections

A. Claims 1-4, 11-19 and 25-38 are not Anticipated by the Garetz Article or the Garetz Article in view of the Merck Index.

Claims 1-4, 11-19 and 25-38 are not anticipated by the Garetz Article, which was also cited against parent application, now Myerson '404. During the prosecution of Myerson '404, the same examiner acknowledged that the Garetz Article does not disclose a method for preparing polymorphs in which the known substance is not urea.

In lieu of resubmitting previous and further arguments that the Garetz Article does not anticipate Claims 1-4, 11-19 and 25-38, Applicant has amended independent Claims 1, 19, and 31 to include a negative limitation that the known substance is not urea. As the examiner has indicated that the Garetz Article does not teach a method in which the known substance is not urea, Applicant submits that Claims 1-4, 11-19, and 25-38 are not obvious over the Garetz Article particularly in light of the inserted negative limitation. As such, Applicant requests that the examiner withdraw the rejection to Claims 1-4, 11-19 and 25-38 based on the Garetz Article.

Further, the Merck Index lends nothing to the Garetz Article to create an anticipation situation, as recognized by the examiner in the prosecution of the parent case. The examiner is referred to the discussion submitted during the prosecution of the parent case. If the examiner would like that discussion repeated, Applicant will be happy to do so upon contact by the examiner.

B. Claims 1, 4, 5, 6, 9, 11-14 and 17 are not Anticipated by Blanks '325 or Blanks '325 in view of the Merck Index.

Claims 1, 4, 5, 6, 9, 11-14 and 17 are not anticipated by Blanks '325, which was also cited during the prosecution of Myerson '404. During the prosecution of Myerson '404, the examiner acknowledged that Blanks '325 does not disclose a method for preparing polymorphs in which the known substance is not an alumina hydrate.

In lieu of resubmitting previous and further arguments that Blanks '325 does not anticipate Claims 1, 4, 5, 6, 9, 11-14 and 17, Applicant has amended independent Claims 1, 19, and 31 to include a negative limitation that the known substance is not alumina hydrate. As the examiner has indicated that Blanks '325 does not teach a

method for creating polymorphs in which the known substance is not alumina hydrate, Applicant submits that Claims 1, 4, 5, 6, 9, 11-14 and 17 are not obvious over Blanks '325 particularly in light of the inserted negative limitation. As such, Applicant requests that the examiner withdraw the rejection to Claim 1, 4, 5, 6, 9, 11-14 and 17 based on Blanks '325.

Further, the Merck Index lends nothing to Blanks '325 to create an anticipation situation, as recognized by the examiner in the prosecution of the parent case. The examiner is referred to the discussion submitted during the prosecution of the parent case. If the examiner would like that discussion repeated, Applicant will be happy to do so upon contact by the examiner.

C. Claims 2, 5-7, 15, 19-23, 25-42 and 44 are not Anticipated by Publication '470.

Publication '470 does not anticipate Claims 2, 5-7, 15, 19-23, 25-42 and 44 because Publication '470 does not disclose every element claimed in the cited claims.

More specifically, Publication '470 discloses a method for the non-photochemical laser induced nucleation in which short high-intensity laser pulses are used to induce nucleation in supersaturated solutions including protein solutions. Publication '470 is directed specifically to the induction of laser nucleation of crystals from solution in which a crystal is nucleated in a particular solution. Publication '470 is not concerned with the production of polymorphs but rather the crystallization or nucleation of a solution without respect to polymorphs. In fact, a person of skill in the art may use Publication '470 to prepare crystals without knowledge of polymorphs.

In contrast, the present invention as claimed is directed towards a method for preparing crystal polymorphs and not for nucleating protein solutions. By claim limitation, the supersaturated solution used in the present invention is subjected to light so to ***“induce the onset of nucleation of the crystal of the polymorph.”*** See independent Claims 1, 19, and 31. As the remainder of the claims are dependent directly or ultimately from one of the independent Claims 1, 19, and 31, each of these dependent claims also includes such a limitation. As such, the present invention is not directed to preparing crystal structures in general or to nucleating crystals, but rather

specifically to preparing crystal structures with a particular polymorph. As a polymorph of a substance can have significantly different properties from another polymorph of the same substance, a person of ordinary skill in the art needs some knowledge of polymorphs to understand the invention.

Further, even if Publication '470 teaches preparing a supersaturated protein solution by a combination of heating, cooling, aging, and treating the solution with a laser, Publication '470 does not suggest or teach such a combination to create polymorphs of a crystal structure. Any such preparation is coincidental. It is this novel concept that is address by the present invention.

As such, Publication '470 cannot and does not anticipate Claims 2, 5-7, 15, 19-23, 25-42 and 44. For these reasons, Applicant requests that the examiner withdraw the rejection based on Publication '470.

8. 35 USC 103 Rejections.

A. Claims 2, 5, 10, 19-21, 25-39 and 45 are not Obvious over the Garetz Article.

Claims 2, 5, 10, 19-21, 25-39 and 45 are not obvious over the Garetz Article because the Garetz Article does not teach the cited claims. More specifically, the Garetz Article does *not* disclose the use of light to induce the onset of nucleation of polymorphs of crystals. Specifically, the Garetz Article discloses that the polarization dependence of the crystallite orientation is consistent with a mechanism in which the electric field of the light plays a major role and that urea molecules are being aligned by the applied optical field, just as they are in the optical Kerr effect, also known as light-induced birefringence. As the examiner correctly notes, the Garetz Article teaches subjecting a supersaturated aqueous urea solution to a laser resulting in the formation of urea crystals. However, nothing in the Garetz Article, as the examiner has acknowledged by allowance of the parent application, teaches such an application to other solutions.

Without Applicant's patent application or blueprint, one of ordinary skill in the art would not prepare a supersaturated solution of known substance, select a polarization of light, subject the solution to the light, and age the solution. See Claims 2, 19, and 31.

The Garetz Article merely teaches the nucleation of urea crystals and the facilitation of the growth of the urea crystals. It was not known at the time of the publication of the Garetz Article (and, indeed, it was not contemplated) whether the urea crystals were the same or different as the known and expected polymorphs. Importantly, there is not a single reference in the Garetz Article that suggests that aging the solution can be used to prepare polymorphs.

As such, Applicant submits that the present invention as claimed in Claims 2, 5, 10, 19-21, 25-39 and 45 are not obvious over the Garetz Article. To further enhance the patentability of the cited claims, Applicant added a negative limitation to independent Claims 1, 19, and 31. As such, Applicant requests that the examiner withdraw the rejection under 35 USC 103 based on the Garetz Article.

B. Claims 10, 15, 16 and 18 are not Obvious over Blanks '325


As Claims 1, 19, and 31 are allowable, Claims 10, 15, 16, and 18 are not obvious over Blanks '325. Specifically, because Claims 10, 15, 16 and 18 are dependant from allowable claims, Claims 10, 15, 16 and 18 are allowable. As such, Applicant requests that the examiner withdraw the rejection under 35 USC 103 based on Blanks '325.

CONCLUSION

Applicant believes it has fully addressed the examiner's concerns and the claims, as amended, are in condition for allowance, and Applicant respectfully requests such action.

If the examiner has any final concerns that can be addressed over the telephone, the examiner is invited to contact the below-signed patent lawyer of record.

Respectfully submitted,



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FIG. 1

